

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 116057 | FOR FURTHER ACTION | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |
| International Application No. PCT/AU2003/001475 | International Filing Date (day/month/year) 7 November 2003 | Priority Date (day/month/year) 7 November 2002 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61F 11/04, A61N 1/36, H04R 25/00 | | |
| Applicant COCHLEAR LIMITED et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

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| Date of submission of the demand 17 February 2004 | Date of completion of the report 7 March 2005 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer JAMES WILLIAMS Telephone No. (02) 6283 2599 |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language* which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages .
- ☐ the claims, Nos. .
- ☐ the drawings, sheets/fig. .

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

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|-------------------------------|--|-----|
| Novelty (N) | Claims 3-14,16-34,37-44,46-61,67-69,80-83 | YES |
| | Claims 1,2,15,35,36,45,62-66,70-79 | NO |
| Inventive step (IS) | Claims 9,10-12,43,50,51,52,54,67,68,80,81,83 | YES |
| | Claims 1-8,13-42,44-49,53,55-66,69-79,82 | NO |
| Industrial applicability (IA) | Claims 1-83 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)**Novelty**

D1: US 5,609,616 A (Schulman et al) 11 March 1997

D1 discloses a physician's testing method for testing implantable cochlear stimulators including 2 processors with an interface to transmit and receive test signals to an implantable cochlear stimulator. The citation further discloses a visual display and a printer connected to the test device.

That the recipient can partially control the tests is not reflected in any particular feature in the claims and can be as little as starting or ending the test as in Claim 30 and while the applicant may argue on the grounds of novelty as not being disclosed in the citation it would nonetheless not involve an inventive step.

Claims 1,2,15,35,36,45,62-66,70-79 are not novel in light of Schuman et al.

Inventive Step

D2: EP 0 124 930 B1 (The Commonwealth of Australia) 20 June 1990

D2 discloses a cochlear implant system for an auditory prosthesis and in which on page 9 lines 20-49 it is disclosed how a recipient of the implant may determine threshold stimulus levels by adjusting a knob and thus disclosing the recipient at least partially control the tests.

Claims 1-8,13-42,44-50,53,55-66,69-79,82,83 do not involve an inventive step in light of D1 when read together with D2.

Claims 3,6,7, 16,17,20,37,40,41,46 and 47 merely define the location of the test module and do not involve an inventive step over the prior art.

Claims 4,5,8,13,14,18,19,21,38,39,42,44,48,49,69 and 82 define the display, storage or transmission of test data by well known means and do not involve an inventive step over the prior art.

Claims 28,32,56 and 60 define a graphical interface which is disclosed in D2.

Claims 22-24 and 26 define the interaction between the two processors which is disclosed in both D1 and D2..

Claims 27,29 and 30 define the recipient interaction with the test as disclosed in D2.

Claims 25 and 53 merely define the first computer as a dumb terminal with no further features.

see continuation of V in Supplemental Box

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

Claim 31 and 59 defines the test set-up by the clinician as disclosed in both D1 and D2.

Claim 33 defines the interface as ageneric port as disclosed in D1 and D2.

Claim 34 and 61 defines an input device for entering control instructions as disclosed in D2.

Claims 55,57, and 58 define the recipient control of tests as disclosed in D2.